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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-423]

Schedules of Controlled Substances: Placement of Three Synthetic Phenethylamines into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration places three synthetic phenethylamines: 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82), and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36), including their optical, positional, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action continues the application of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse

distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe.

DATES: Effective: [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.” The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA. 28 CFR part 0, appendix to subpart R.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated on the Attorney General’s own motion, as delegated to the Drug Enforcement Administration, and is supported by, *inter alia*, a recommendation from the

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Services (HHS) in carrying out the Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

Assistant Secretary for Health of the HHS ² and an evaluation of all relevant data by the DEA. This action continues the application of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles, or proposes to handle, 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe.

Background

On October 10, 2013, the DEA published a notice of intent to temporarily place 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82), and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) into schedule I pursuant to the temporary scheduling provisions of the CSA. 78 FR 61991. On November 15, 2013, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these three synthetic phenethylamines into schedule I of the CSA. 78 FR 68716. That final order was effective on the date of publication, and was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these three synthetic phenethylamine substances was necessary to avoid an imminent hazard to public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA requires that the temporary scheduling of a substance expire two years from the effective date of the scheduling order, or on or before November 14, 2015. 21 U.S.C. 811(h)(2). However, the CSA also provides that the temporary scheduling may be extended for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1). *Id.* Accordingly, on November 13, 2015, the DEA published a notice of proposed rulemaking (NPRM) to

permanently control 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in schedule I of the CSA. 80 FR 70649. Specifically, the DEA proposed to add these substances to 21 CFR 1308.11(d), hallucinogenic substances. Also, on November 13, 2015, the DEA extended the temporary scheduling of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe by one year, until November 13, 2016. 80 FR 70658.

DEA and HHS Eight Factor Analyses

On August 12, 2015, the HHS provided the DEA with three scientific and medical evaluation documents prepared by the FDA entitled “Basis for the Recommendation to Place 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe) and its Salts in Schedule I of the Controlled Substances Act (CSA);” “Basis for the Recommendation to Place 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe) and its Salts in Schedule I of the Controlled Substances Act (CSA);” and “Basis for the Recommendation to Place 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe) and its Salts in Schedule I of the Controlled Substances Act (CSA).” After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe be controlled in schedule I of the CSA. In response, the DEA conducted its own eight-factor analysis of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe. Both the DEA and HHS analyses are available in their entirety under the tab “Supporting Documents” of the public docket of this action at <http://www.regulations.gov> under FDMS Docket ID: DEA-2015-0019 (Docket Number DEA–423).

Determination to Schedule 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe

After a review of the available data, including the scientific and medical evaluations and the scheduling recommendations from the HHS, the DEA published an NPRM entitled “Schedules of Controlled Substances: Placement of Three Synthetic Phenethylamines into Schedule I,” proposing to control 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in schedule I of the CSA. 80 FR 70649, November 13, 2015. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before December 14, 2015. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before December 14, 2015.

Comments Received

The DEA received no comments on the proposed rule to schedule 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe.

Scheduling Conclusion

After consideration of the scientific and medical evaluations and accompanying recommendations of the HHS, and the DEA’s consideration of its own eight-factor analyses, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe. As such, the DEA is permanently scheduling 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

- (1) 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have a high potential for abuse that is comparable to other schedule I substances such as 2C-I, 2C-C, 2C-B, LSD and DOM;
- (2) 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have no currently accepted medical use in treatment in the United States; and
- (3) There is a lack of accepted safety for use of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe under medical supervision.

Based on these findings, the Administrator of the DEA concludes that 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82), and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36), including their optical, positional, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe

25I-NBOMe, 25C-NBOMe, or 25B-NBOMe are currently scheduled on a temporary basis in schedule I² and are therefore currently subject to the CSA regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, conduct of instructional activities or chemical analysis, and possession of schedule I controlled substances, including those listed below. These controls will continue on a permanent basis:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe, or who desires to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.
2. *Disposal of Stocks.* 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.
3. *Security.* 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe continue to be subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71–1301.93.
4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe must be in compliance with

² 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 80 FR 70658, Nov. 13, 2015.

21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant required to keep records and who possesses any quantity of 25I-NBOMe, 25C-NBOMe, and/or 25B-NBOMe is required to maintain an inventory of all stocks of NBOMes on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to 25I-NBOMe, 25C-NBOMe, and/or 25B-NBOMe pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1317.

Manufacturers and distributors must submit reports regarding 25I-NBOMe, 25C-NBOMe, and/or 25B-NBOMe to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33.

8. *Order Forms.* Every DEA registrant who distributes 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe not authorized by, or in violation of, the CSA or its implementing regulations continues

to be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On November 15, 2013, the DEA published a final order to temporarily place these three synthetic phenethylamines into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 78 FR 68716. On November 13, 2015, the DEA published a final order extending the temporary placement of these substances in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). 80 FR 70658. The DEA estimates that all entities handling or planning to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe are currently registered to handle these substances. There are currently 18 registrations authorized to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 18 registrations represent 13 entities, of which 6 are small entities. Therefore, the DEA estimates six small entities are affected by this rule.

A review of the 18 registrations indicates that all entities that currently handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe handle other schedule I controlled substances,

and have established and implemented (or currently maintain) the systems and processes required to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the six affected small entities. Therefore, the DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Amend § 1308.11 by:

- a. Adding paragraphs (d)(55) through (57); and
- b. Removing paragraphs (h)(1) through (3) and redesignating paragraphs (h)(4)

through (20) as (h)(1) through (17), respectively.

The additions read as follows:

§ 1308.11 Schedule I.

* * * *

(d) * *

(55) 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe, 2C-I-NBOMe).....(7538)

(56) 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe, 2C-C-NBOMe).....(7537)

(57) 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe, 2C-B-NBOMe).....(7536)

* * * *

Dated: September 15, 2016

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016-23185 Filed: 9/26/2016 8:45 am; Publication Date: 9/27/2016]